

BOARD OF PHARMACY
MEETING MINUTES
January 24, 2006

ROLL CALL

Richard Zarek, R.P., Chair, called the meeting of the Board of Pharmacy to order at 8:00 a.m. in the Staybridge Room of the Staybridge suite, located at 2701 Fletcher Avenue, Lincoln, NE. Copies of the agenda were sent to Board members and other interested parties prior to the meeting. The following Board members answered the roll call:

Richard Zarek, R.P., Chairperson
C. Curtis Barr, R.P. Vice-Chairperson
Kevin Borchert, R.P., Secretary
Roger Kaczmarek, R.P.
Linda Labenz

A quorum was present and the meeting convened. Also present from the Department were: Becky Wisell, Section Administrator; Vonda Apking, Credentialing Coordinator; Cecilia Curtis-Beard, Credentialing Specialist; Pharmacy Inspectors: Tony Kopf, R.P., Ronald Klein, R.P., and Mike Swanda, R.P.; Duane Newland and Jeff Newman, Investigators and Michael Grutsch, Program Manager, from the Investigations Division; and Lisa Anderson, Assistant Attorney General.

REVIEW OF AGENDA

Additions, Modifications, Reordering and Adoption of Agenda

The Board requested that the following items be removed from the consent agenda for further discussion: the renewal application of Walgreen's Healthcare Plus, Mail Service Pharmacy License #443 and the reinstatement application of Vicki Long.

Borchert moved, seconded by Labenz, to approve the agenda with the Chairperson having the authority to rearrange as needed. Voting aye: Barr, Borchert, Kaczmarek, Labenz, Zarek. Voting nay: None. Motion carried.

Adoption of the Consent Agenda

Labenz moved, seconded by Barr, to approve the consent agenda as amended. Voting aye: Barr, Borchert, Kaczmarek, Labenz, Zarek. Voting nay: None. Motion carried.

ELECTION OF OFFICERS

Kaczmarek moved, seconded by Labenz, to nominate C. Curtis Barr, R.P., as Chairperson, Kevin Borchert, R.P., as Vice-Chairperson and Linda Labenz as Secretary. Voting aye: Barr, Borchert, Kaczmarek, Labenz, Zarek. Voting nay: None. Motion carried.

DISCIPLINARY INFORMATION (ACTIONS TAKEN AND PENDING)— CONSENT

Name	Actions Taken and/or Pending	Alleged Violation
Bader, Tom	Hearing 1/31/06	Denial of initial licensure due to disciplinary action in another state.
Crane, Gary R.	Petition for Reinstatement 9/30/05 Order on Reinstatement 12/19/05	Disciplinary action in another state.
Dvorak, Lauri J.	Petition for Disciplinary Action 9/21/05 Amended Petition for Disciplinary Action 10/12/05 Order on Agreed Settlement 1/4/06	Alleged theft of controlled substances from her place of employment, possession of Ambien (a controlled substance) without a valid prescription, failure to secure a Schedule II controlled substance in a locked cabinet.
Potmesil, Howard Shannon	Petition for Disciplinary Action & Temporary License Suspension 6/30/05 Order for Temporary License Suspension 7/1/05 Hearing 7/12/05	Misrepresentation of material facts in procuring a license, theft of pharmaceuticals from place of employment, possession of Ativan for own use without a prescription, admitted to hospital for manic-depression, reported to emergency room staff that he may do harm to himself and family.
Pranno, Faith Mary	Petition for Disciplinary Action 10/4/05	Dispensed a medical order for "Brookhouser Solution" compounded by a pharmacy technician. The solution dispensed was compounded using 176 mg of Atropine instead of 0.176 mg. Admitted that she was the pharmacist responsible for verifying the accuracy of the medical order.
Stachowaik, Charles	Findings of Fact, Conclusions of Law and Order 11/22/0 Denial upheld 11/28/05	Denial of initial licensure because of disciplinary action taken against his Florida license.
Turner, Fred A.	Petition to Revoke Probation 11/10/05 Amended Petition to Revoke Probation 12/9/05	UA tested positive for ethanol; failure to provide proof of attendance at support group meetings; failure to submit monthly reports of the use of controlled substances.
Wells, James	Petition for Disciplinary Action 10/24/05 Agreed Settlement 10/17/05 Order Rejecting Agreed Settlement	Audit results showed significant losses of controlled substances; failure to keep accurate records of receipt and disposition of controlled substances.

(10A) Pharmacist Intern Applications with Misdemeanor/Felony Convictions (3)**(10B) Reinstatement of a Pharmacist License After Non-Disciplinary Revocation of More Than One Year (1)****(10C) Mail Service Pharmacy Renewal with Past Disciplinary Action (3)**

- (11) Pharmacy Technician Manuals (1)
(12) Pharmaceutical Care Agreements (3)

**INVESTIGATIONAL REPORTS, DISCIPLINARY REPORTS, AND CONTROLLED SUBSTANCES
AUDIT REPORTS—CLOSED SESSION**

Zarek moved, seconded by Labenz, to close the session at 8:05 a.m. to receive investigation reports, disciplinary reports, and controlled substances audit reports. Voting aye: Barr, Borchert, Kaczmarek, Labenz, Zarek. Voting nay: None. Motion carried.

Labenz recused herself from the meeting at 9:07 a.m.

Labenz returned to the meeting at 9:10 a.m.

Kaczmarek recused himself from the meeting at 9:10 a.m.

Zarek recused himself from the meeting at 9:22 a.m.

Kaczmarek returned to the meeting at 9:25 a.m.

Zarek returned to the meeting at 9:40 a.m.

Kaczmarek moved, seconded by Labenz, to reopen the session at 10:28 a.m. Voting aye: Barr, Borchert, Kaczmarek, Labenz, Zarek. Voting nay: None. Motion carried.

FAXED PRESCRIPTION FOR CONTROLLED SUBSTANCES – ROGER BRINK

Roger Brink, Department Legal, joined the meeting at 10:29 a.m.

Joni Cover, Nebraska Pharmacist Association (NPA) addressed the Board. Ms. Cover stated she was receiving calls from pharmacists throughout Nebraska regarding the article in the Board of Pharmacy Newsletter, dated November 2005, regarding faxed prescriptions. Ms. Cover asked the Board for clarification regarding the difference of an unsigned faxed prescription and someone calling in a prescription for controlled substances III-V.

Zarek explained that if a pharmacist receives a fax for a controlled substances III-V, that is unsigned, then the pharmacist can only dispense the prescription after the prescriber is called back to verify. Ms. Cover asked if an oral prescription means to verify. Zarek stated according to the statute, the pharmacist must call the prescriber and obtain an oral verification and then he/she can dispense the prescription. Klein added that if the prescription is not signed, call the prescriber to get an oral verification, write on the prescription that the prescription was verified and then the pharmacist could dispense. Zarek answered that it is ok to dispense if it is a signed controlled substances III-V prescription.

Ms. Cover stated that maybe the newsletter should say, “faxes of unsigned controlled substances III-V prescriptions have to be verified”. The Board agreed.

Brink stated a prescription can be either written (original prescription or a fax of the original signed prescription) or oral. If it is not signed, then it is not a written prescription. If a doctor writes a prescription but does not sign it, then it does not qualify as a written prescription. As long as it is signed, then it is considered a written prescription.

Brink added that in Statute 28-414 (2b) states “A controlled substance listed in Schedule III, IV, or V of section 28-405 may be dispensed pursuant to a facsimile of a written, signed prescription. The facsimile of a written, signed prescription shall serve as the original written prescription for purposes of this subsection and shall be maintained in accordance with the provisions of subdivision (3)(c) of this section.”

Kopf stated that the Board had asked for written clarification regarding the word “communication” and according to DEA, “communication” means verbal. Brink said there is enough ambiguity in the statutes to allow the Board to interpret the statute.

Brink added that the Board’s interpretation of the statute is that the method of communication for a controlled substance prescription must be oral is acceptable. Brink added that the statutes do not require a prescription for a legend drug to be signed.

Ms. Cover clarified that the Board's interpretation that a facsimile of an unsigned CS III, IV or-V, could be treated as an oral prescription but must be verified by the pharmacist. The Board agreed but stated that the newsletter should read "a facsimile of an unsigned CS III, IV or-V, can be treated as an oral prescription, but must be verified".

Ms. Cover asked the Board if a digital signature is accepted. The Board agreed that digital signature is acceptable but not an electronic signature for a controlled substance prescription. Ms. Cover asked if a prescription has an electronic signature, would the pharmacist have to print it out and then verify the prescription? The Board agreed that the prescription would have to be verified. Barr said by verifying it, the prescription would then become an oral prescription.

Ms. Cover thanked the Board for the clarification. Zarek mentioned that any questions for the Board should be forwarded to the Board in writing prior to the meeting.

Roger Brink left the meeting at 11:00 a.m.

APPROVAL OF MINUTES

November 7, 2005

Page 1: Labenz commented that under Review of Agenda, first paragraph, line 2, delete the first word "Crane".

Page 2: There were no changes.

Page 3: Borchert commented under Application Review, third paragraph, second bullet, replace the first word "of" with the word "or".

Page 4: Borchert commented that the second bullet should also have the same change as page 3.

Page 5: Labenz commented that under Practice Act Changes, paragraph 4, line 2, add the word "date" after the word "effective" and in line 4, delete the "s" from the second word "terms" and add the word "to" right after.

Page 6: Zarek commented that in the first paragraph, line 9, add the word "two" after the second word "last" and in line 10, it should read "request an Attorney". Borchert commented that under 172 NAC 129 Delegated Dispensing Regulations, third paragraph, line 2, add the word "the" after the word "but".

Page 7: Zarek commented that in the fourth paragraph, line 4, the word "opening" should be "operating", that in line 7 the first "the" should be "that", and in line 9, add the word "a" before the word "prescriber".

Page 8: Zarek commented that in the second paragraph, line 2, the word "braking" should be "breaking". Zarek also commented that the title "Board of Nursing" should be clarified as to what the actual topic was. Also, under Other Mechanisms for Determining Continued Competency, first paragraph, line 1, the word "list" should be "lists", the word "alternative" should be "alternatives", and the word "determined" should be "determine"; also, first paragraph, line 5, the word "efficient" should be "sufficient"; also, in the second paragraph, line 3, delete the word "the" before the word "meeting". Labenz commented that also in the second paragraph, line 4, add the word "professional" before the word "Board".

Page 9: Zarek commented that under Formulary Advisory Committee, line 2, the word "re-appointment" should be "appoint".

Page 10: There were no changes.

Zarek moved, seconded by Labenz, to approve minutes from November 7, 2005 as amended. Voting aye: Barr, Borchert, Kaczmarek, Labenz, Zarek. Voting nay: None. Motion carried.

November 22, 2005 – Conference Call

Page 1: There were no changes.

Page 2: Borchert commented under Application Review, third paragraph, fourth bullet, replace the first word "of" with the word "or".

Page 3: There were no changes.

Zarek moved, seconded by Labenz, to approve the conference call minutes from November 22, 2005. Voting aye: Barr, Borchert, Kaczmarek, Labenz, Zarek. Voting nay: None. Motion carried.

APPLICATION REVIEW - CONSENT

Borcher moved, seconded by Zarek, to approve the application for reinstatement of Vicki Long. Voting aye: Barr, Borcher, Kaczmarek, Labenz, Zarek. Voting nay: None. Motion carried.

Labenz moved, seconded by Borcher, to refuse to renew Walgreen's Mail Service, license #443, due to not employing a Nebraska licensed pharmacist and having disciplinary action taken against their Louisiana license. Voting aye: Barr, Borcher, Kaczmarek, Labenz, Zarek. Voting nay: None. Motion carried.

PHARMACY TECHNICIAN MANUALS (1) – CONSENT

PHARMACEUTICAL CARE AGREEMENTS (3) – CONSENT

LEGISLATION

Uniform Licensing Law (ULL) Rewrite

Wisell stated that the ULL rewrite will not be introduced during the 2006 legislative session. She also added that they were all disappointed with this decision. No reason was given as to why the ULL will not be introduced. Wisell commented that there were concerns with losing the support of stakeholders.

Wisell mentioned that Senator Jensen, Chairman of the Health & Human Services Committee, introduced LB 1177. This bill was Senator Jensen's way of strongly urging the legislature to introduce this legislation in the 2007 legislative session. Wisell mentioned that there would be a hearing on LB 1177 on February 10th. Barr asked if the department plans to testify at the hearing. Wisell stated that she was not asked to review this bill and she was unsure the position the department was taking on this bill.

Practice Act Changes

The Board will continue to work on the proposed changes of the Practice Act.

Wholesale Drug Distribution Act (LB 318)

Wisell informed the Board that LB 318 was a carryover bill from the 2005 legislative session. The bill was amended (AM 1815) and placed on general file on January 9, 2006.

Wisell shared a copy of a letter from David Gonzales from Healthcare Distribution Management Association (HDMA), which included comments regarding the proposed amendment.

Ms. Russell addressed the Board with her concerns with the proposed amendment.

Ms. Russell requested that the Board modify the definition of normal distribution to include from one wholesaler to another wholesaler. Ms. Russell stated there were circumstances, such as a shortage of drugs in certain areas, that would be considered as emergencies, when Cardinal Health would need to supply the drug to another wholesaler to cover that shortage. The Board is in favor of the definition of "normal distribution channel" in AM 1815.

The letter received from HDMA mentioned several other sections of AM 1815 where HDMA had some concerns. The Board agreed with HDMA's request to change the language in section 36 of AM 1815, to include separate penalties for knowingly and unknowingly violating the act. The Board will notify Kelly Boryca, Pfizer, of this request. The Board will send a letter in support of AM 1815 with the amended language mentioned above. **Action Item: Barr will write the letter of support and send it to the Department to send to the Health and Human Services Committee.**

Other Legislation

Wisell stated Senator McDonald introduced LB 1116, which amends language in the Cancer Drug Repository Program Act. The Board did not agree with proposed changes. Borchert and Kaczmarek volunteered to testify at the scheduled hearing on February 2, 2006. **Action Item: Borchert and Kaczmarek will testify at the February 2, 2006 hearing on LB 1116.**

Borchert updated the Board about the meeting with Senator McDonald concerning LB 1079.

Wisell commented that she performed a survey of the registered participants of the Cancer Drug Repository Program. The results were shared with interested parties.

Ms. Cover mentioned that the NPA plans to oppose both LB 1079, Immunosuppressant Drug Repository Program Act and LB 1116 and has asked directors of the transplant centers to also oppose LB 1079. Ms. Cover also provided the Board with a handout updating the Board on the NPA's position on several other bills of interest.

Kelly Boryca, Pfizer, addressed the Board concerning LB 318. Ms. Boryca asked for the Department's support in attaching this bill to another germane bill in order to get it passed this session. The Board mentioned the request from the earlier discussion. Ms. Boryca agreed. Labenz moved, seconded by Zarek, to approve the idea of amending LB 318 into another germane bill in order to get it passed this session. Voting aye: Barr, Borchert, Kaczmarek, Labenz, Zarek. Voting nay: None. Motion carried.

The Board thanked Ms. Boryca for all her efforts with LB 318. The Board also thanked Ms. Cover for her update.

Immunosuppressant Drug Repository Program Act (REQ 1441)

Megan McCartan, R.P., and Laurel Williams-Salonen, UNMC Liver/Intestinal Transplant Center addressed the Board. They explained the background of the bill and why they support LB 1079.

The Board mentioned that there are other programs available for free or reduced cost drugs for these situations. These programs would be safer for the patient.

The Board thanked Ms. McCartan and Ms. Williams-Salonen for their information.

REGULATIONS DEVELOPMENT – 175 NAC 8 REGULATIONS GOVERNING PHARMACIES

Wisell informed the Board that there are changes being proposed regarding the 175 NAC 8 Regulations Governing Pharmacies. The changes are as follows:

- Fees - The proposed initial licensing fee for a pharmacy will increase to \$625.00. The renewal fee, which is due July 1st of each year, will also be increase to \$625.00.
- Inspections – Wisell explained several changes to the Compliance Inspection section of the regulations.
- Disaster preparedness – Wisell informed the Board that there will now be a Disaster Preparedness and Management requirement for all facilities.

Zarek mentioned his concern with increasing the fee would limit access to pharmacies in rural communities. Wisell stated a notice has been sent to all interested parties. Wisell also informed the Board that there is a scheduled meeting on January 30th at the State Office Building, LLF, 1-4:00 p.m. regarding the proposed changes to the facility regulations.

PHARMACY TECHNICIANS

Zarek informed the Board that the 407 review for registering pharmacy technicians was completed and the recommendation was that pharmacy technicians should be registered. The Board commented that statutory language should be developed and introduced during the 2007 legislative session. Wisell commented that Dr. Schaefer's review included a request for mandatory reporting of pharmacy technicians. Wisell added that the proposed language must be submitted to the Department by June. The Board questioned who would introduce this legislation. Barr stated he would like to review statutes from other states regarding pharmacy technicians. Labenz suggested that they receive only four samples from the surrounding states. **Action Item: Staff to gather this information and forward to the Board. Wisell will talk to Dave Montgomery and Ron Briel about the process.**

TELEPHARMACY

Beth Robey, R.P., Hope Pharmacy and Griff Danheim, AmeriSource Bergen addressed the Board regarding telepharmacy. Ms. Robey explained that Hope Pharmacy would like to use Telepharmacy with a facility located 14 miles from Council Bluffs in Iowa. Hope Pharmacy has contacted the Iowa Board of Pharmacy and were informed that they would need to employ an Iowa licensed pharmacist for the facility in Iowa even if that pharmacist is located in Nebraska.

Mr. Danheim explained the technical procedures and aspects of telepharmacy to the Board.

The Board commented that current statutes would not allow telepharmacy to happen in Nebraska. Ms. Cover volunteered the NPA to establish a workgroup for discussing telepharmacy. Danheim informed the Board if there are any additional questions regarding this issue, to contact him. **Action Item: Barr stated that the Board would contact the Iowa Board of Pharmacy and obtain their statutes on this subject.**

REQUEST FOR ADDITIONS TO THE EMERGENCY DRUG BOX APPROVED LIST

The Board reviewed a request for additions to the emergency drug box approved list from Mary Pehling, R.P., NCS HealthCare. Zarek moved, seconded by Borchert, to deny the request for Warfarin 1 mg #10, Vitamin K inj/tab, Sodium Chloride .45% 500 ml IV Bag, and Insulin Novolin R, N, 70/30 because they are item of convenience. Voting aye: Barr, Borchert, Kaczmarek, Labenz, Zarek. Voting nay: None. Motion carried.

The Board noted that Sodium Chloride .9% 500ml IV Bag and Sodium Chloride .9% w/KCI 10meq IV Bag are already on the approved list in some form. The Board requested Ms. Pehling be informed that any further requests should be given to either the Nebraska Medical Directors Association or the Nebraska Association of Consulting Pharmacists for a collective recommendation to the Board.

PRESCRIPTION DRUG MONITORING PROGRAM (PMP) GRANT

Barr commented that he was still waiting on information from Iowa. Klein stated that in order for the Board to receive funding for spring from the Planning Grant, the Board would have to submit language by January 31st. If the state statutes do not address, then the federal statutes will require a PMP program. **Action Item: The Board agreed that Klein will check on the deadline of this grant and the 2006 meeting dates regarding this grant, and forward the information to the Board members.**

PATIENT SAFETY RFP

Wisell informed the Board that accounting has brought to the attention of the Division that projects have exceeded the current cash spending authority. The Department will be asking for an increase in the cash spending authority in the next legislative session. Wisell explained that the Board will need to reduce the Dyke Anderson-Patient Safety Grant to \$50,000. Kaczmarek moved, seconded by Labenz, to have the Dyke Anderson-Patient Safety Grant reduced to \$50,000 and publicized for bids as soon as possible. Voting aye: Barr, Borchert, Kaczmarek, Zarek.

Voting nay: None. Motion carried. The Board agreed to offer \$50,000 again next year. **Action Item: Staff will amend the RFP proposal and publish.**

NABP ISSUES

Request for Proposed Amendments to NABP's Constitution and Bylaws

The Board had no recommendations at this time.

NABP Annual Meeting – San Francisco, April 8-11, 2006

Zarek moved, seconded by Labenz, to reimburse all the Board members and one pharmacy inspector for their travel expenses to attend the NABP Annual Meeting in San Francisco April 8-11, 2006. Voting aye: Barr, Borchert, Kaczmarek, Labenz, Zarek. Voting nay: None. Motion carried. Barr mentioned that his travel expenses will be paid by NABP. **Action Item: Staff to prepare travel authorizations for the Board members and Kopf to attend the annual NABP meeting.**

Board Support for NABP President - Elect

Zarek moved, seconded by Labenz, for the Board to send a letter of support for Barr's candidacy for NABP's president-elect. Voting aye: Barr, Borchert, Kaczmarek, Labenz, Zarek. Voting nay: None. Motion carried. Barr commented that NABP has certain rules and requested that the Board not send the letter until he checks on the rules. Barr thanked the Board for their support.

FDA Workshop on Protecting Patients from Counterfeit Drugs and Request for Written Comments

The Board discussed sending written comments and a copy of LB 318. **Action Item: Barr will put together written comments and forward to the Department.**

COMMITTEE REPORTS

MPJE Committee

Kaczmarek and Klein attended an Item Writing Workshop last week. They reviewed a total of 1,886 questions and 1,142 questions were updated and will go into the pre-test pool.

Tri-Partite Committee on Internship

Nothing to report at this time.

Formulary Advisory Committee

Wisell informed the Board that she has not been able to discuss Ms. Dering-Anderson's resignation with her. The Board needs to nominate someone to this committee. Ms. Cover recommended Brenda Kiolbasa, R.P. Wisell will inform Joyce Novak that Ms. Kiolbasa might be interested and if she is not then the Board will advertise to fill the position.

FINANCIAL REPORT

Zarek questioned the amount under the Indirect cost Allowance. Wisell will get an explanation from accounting. **Action Item: Wisell will get an explanation from accounting on the amount under Indirect Cost Allowance.**

ACTION ITEMS

Letter to Dr. Schaefer Requesting and Attorney General's Opinion on the Meaning of "Recommendation"

Wisell stated that Dr. Schaefer did not seek an Attorney General's (AG) opinion on the meaning of "recommendation".

Multiple C-II Prescriptions Written at the Same Time

The Board agreed that the DEA's position should be included in the newsletter. **Action Item: Newsletter article on DEA's position on multiple C-II prescriptions written at the same time.**

NABP Mailbag Survey on Pyxis Machines in Long-term Care Facilities

Borcher moved, seconded by Labenz, to pursue legislation to allow the use of automated drug-dispensing machines in Long-term Care Facilities (LTC's). Voting aye: Barr, Borcher, Kaczmarek, Labenz, Zarek. Voting nay: None. Motion carried. **Action Item: Board will develop proposed language for legislation.**

INVESTIGATIONAL REPORTS, DISCIPLINARY REPORTS, AND CONTROLLED SUBSTANCES AUDIT REPORTS—CLOSED SESSION CONT'D

Zarek moved, seconded by Labenz, to close the session at 3:50 p.m. to receive controlled substances audit reports. Voting aye: Barr, Borcher, Kaczmarek, Labenz, Zarek. Voting nay: None. Motion carried.

Labenz moved, seconded by Kaczmarek, to reopen the session at 4:45 p.m. Voting aye: Barr, Borcher, Kaczmarek, Labenz, Zarek. Voting nay: None. Motion carried.

MILLARD PUBLIC SCHOOLS UPDATE ON ASTHMA PROJECT

Barr stated that there had been only three incidents where rescue squads were called to the schools.

CORRESPONDENCE

The Board requested that a resolution in Dyke Anderson's memory be sent to NABP. Action Item: Staff will prepare a resolution and send to NABP. Labenz mentioned that she would not be able to attend the March meeting. The Board re-scheduled the March meeting to March 6, 2006.

ADJOURNMENT

Zarek moved, seconded by Labenz, to adjourn the meeting at 4:56 p.m. Voting aye: Barr, Borcher, Kaczmarek, Labenz, Zarek. Voting nay: None. Motion carried.

Respectfully submitted,

(Signature on file with the Department)

Linda Labenz, Secretary
Board of Pharmacy